UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

D.P., Plaintiff, v. JUUL LABS, INC., Defendant.	No. 7:18-CV-05758 (CS) Oral Argument Requested

DEFENDANT'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

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PRELIMINARY STATEMENT

"Tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths every single year. In addition to the devastating human toll caused mainly by cigarette smoking, tobacco also causes substantial financial costs to society, with direct health care and lost productivity costs totaling nearly $300 billion a year." Ex. 1, at 1 (FDA Press Release, July 28, 2017);[1] *see also* 21 U.S.C. § 387 note (finding that cigarette smoking is "the foremost preventable cause of premature death in America"). While it is well known that nicotine is the addictive property in cigarettes, "[n]icotine . . . is not directly responsible for the tobacco-caused cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year." Ex. 2, at 2 (FDA Comm'r Scott Gottlieb, "A Nicotine-Focused Framework for Public Health"). Rather, the toxic chemical compounds in tobacco products—and particularly in the smoke created by setting tobacco on fire—are directly and primarily responsible for the illness and death caused by cigarettes. *See* Ex. 3, at 6 (FDA 2018 Strategic Policy Roadmap). Cigarette smoke contains over 7,000 chemicals, at least 250 of which are known to be harmful and at least 69 of which can cause cancer. *See* Ex. 4, at 1 (Nat'l Cancer Ctr., "What Harmful Chemicals Does Tobacco Smoke Contain?"). Consequently, cigarettes remain the only consumer product that, when used as intended, will kill half of all long-term users. *See* Ex. 5, at 1 (Am. Cancer Soc'y, "Health Risks of Smoking Tobacco").

"Envisioning a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of [prevention] efforts." Ex. 1, at 2. According to the Food

[1] All Exhibits ("Ex.") cited herein refer to the exhibits attached to the accompanying Declaration of Austin V. Schwing.

and Drug Administration ("FDA")—the agency that Congress has tasked with evaluating and regulating tobacco-related public health issues—electronic nicotine delivery systems ("ENDS") may offer an "alternative to cigarettes for adults who still seek access to satisfying levels of nicotine, without all the deadly effects of combustion." Ex. 6, at 2 (FDA Press Release, Nov. 15, 2018).

ENDS, including the JUUL Labs, Inc. ("JLI") products at issue in this case ("JUUL products"), create a vapor—not smoke—and do so without combustion. According to the FDA, "[t]he inhalation of nicotine (i.e., nicotine without the production of combustion) is of less risk to a user than the inhalation of nicotine delivered by smoke from combusted tobacco products," and "switching from combusted cigarettes to ENDS may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products[.]" 81 Fed. Reg. 28974, 29030, 209033 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140, 1143).

As discussed more fully below, the FDA is planning and regulating in this space with these realities in mind. Indeed, the FDA has expressly stated that "our plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources." Ex. 7, at 3 (FDA Press Release, Mar. 15, 2018). JUUL products are legal in the United States, are actively regulated by the FDA, and are one of the alternative sources of nicotine for current adult smokers. Nevertheless, Plaintiff D.P., a minor who alleges he obtained JUUL products from unidentified third parties who unlawfully provided those products to him, effectively asks this Court to usurp the FDA's authority over ENDS to outlaw JUUL products in

the guise of a product liability suit. Plaintiff's Amended Complaint (*see* Dkt. No. 53, "FAC") brings three claims, but each fails as a matter of law.

First, Plaintiff's design defect claim does not adequately plead a cognizable design defect or a feasible alternative design that would be as satisfying to adult smokers, and fatally concedes that D.P.—a minor for whom JUUL products were never intended—did not use those products in their intended manner. Second, the failure to warn claim is preempted by 21 U.S.C. § 387p(a)(2)(A) and FDA regulations that mandate the specific warning labels that appear on JLI's products. Moreover, that claim ignores JUUL products' clear statements that they should not be used by minors and contain nicotine, and Plaintiff does not allege that he believed it was appropriate for him to use JUUL products or that he lacked the common knowledge that nicotine is addictive. Third, the negligent design and marketing claim fails to properly plead duty, breach, or causation, most notably because the FAC is devoid of any claim that Plaintiff ever saw—much less relied upon—any of the challenged marketing campaigns. Given that Plaintiff has already had an opportunity to amend his defective complaint, each claim should be dismissed with prejudice.

FACTUAL BACKGROUND

JLI is a San Francisco-based company that designs, manufactures, and markets ENDS. As the FAC acknowledges, JUUL products are "intended for smokers," FAC ¶ 94, specifically adult smokers who want to obtain nicotine without ingesting many of the harmful substances commonly found in combustible cigarettes. The FAC noticeably tries to ignore the labeling on JUUL products because it undermines each of Plaintiff's three causes of action. The packaging for JUULpods stated:

- It is "the alternative for adult smokers";
- It is "**NOT FOR SALE TO MINORS. Keep away from children and pets**";

- That "1 JUULpod contains – 0.7mL with 5% nicotine by weight //approximately equivalent to about 1 pack of cigarettes"; and that

- "This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm."

Ex. 8 (2017 JUULpod packaging) (emphasis in original).[2]

ENDS, including JUUL products, are heavily regulated by the FDA. On May 10, 2016, the FDA issued the Final Rule (also known generally as the "Deeming Regulations"), which deems e-cigarettes to be "tobacco products" and concludes that they fall under the FDA's authority to regulate tobacco products. *See* Final Rule, 81 Fed. Reg. at 28976. The Final Rule also requires that as of August 10, 2018, "[p]ackaging and advertising for all newly deemed products other than cigars must display an addictiveness warning that states: 'WARNING: This product contains nicotine. Nicotine is an addictive chemical.'" Final Rule, 81 Fed. Reg. at 28988; *see also* 21 C.F.R. § 1143.3(a)(1). Further, federal law expressly prohibits states from imposing requirements "different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." 21 U.S.C. § 387p(a)(2)(A). Thus, as addressed in detail below, Congress and the FDA have expressly preempted claims based on what is or could be included on ENDS labels.

[2] Where, as here, a label serves as a basis for a claim, the label is "integral to . . . the [complaint]" and therefore "can be considered on [a motion to dismiss]." *In re Mirena IUD Prods. Liab. Litig.*, 29 F. Supp. 3d 345, 350 (S.D.N.Y. 2014); *see also*, *e.g.*, *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 175 (S.D.N.Y. 2016) (concluding that a product label was integral to a complaint alleging product liability claims). Furthermore, the FDA-approved warning labels at issue here are subject to judicial notice. *See*, *e.g.*, *Gagnon v. Alkermes PLC*, No. 17-cv-9178, 2019 WL 1388700, at *4 (S.D.N.Y. Mar. 28, 2019) (collecting relevant cases).

On March 21, 2018, the FDA issued an advanced notice of proposed rulemaking to examine "how certain flavors may help adult cigarette smokers reduce cigarette use and switch to potentially less harmful products," balanced against potential usage by minors. 83 Fed. Reg. 12294 (Mar. 21, 2018). On November 15, 2018, the FDA announced new measures to combat underage use of nicotine products nationwide. *See* Ex. 6. The FDA Commissioner acknowledged "the opportunity to advance new technologies like [ENDS] as an alternative to cigarettes for adults who still seek access to satisfying levels of nicotine, without all the deadly effects of combustion." *Id.* at 2. Nevertheless, to discourage underage use of ENDS, he directed the FDA to consider "having all flavored ENDS products (other than tobacco, mint and menthol flavors or non-flavored products) sold in age-restricted, in-person locations and, if sold online, under heightened practices for age verification." *Id.* at 4. The exclusion of mint- and menthol-flavored ENDS "reflect[ed] a careful balancing of public health considerations," because "the availability of these flavors in ENDS may be important to adult smokers seeking to transition away from cigarettes." *Id.* at 4–5. On March 14, 2019, the FDA published draft guidance to implement these changes and requested comments by April 15. *See* Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry; Availability; 84 Fed Reg. 9345 (Mar. 14, 2019) ("Draft Guidance").

There is no dispute that JLI has adhered to all of the FDA's relevant mandates and regulations, and Plaintiff does not allege otherwise. Rather, against this backdrop, the FAC seeks to have this Court declare JUUL products defective because they contain nicotine and deliver it in a way that is palatable—exactly the elements that make the product a viable alternative to combustible cigarettes for existing adult smokers. But Plaintiff is not an intended user of the JUUL products: he is a minor. FAC ¶ 63. Moreover, Plaintiff does not allege that

JLI provided him with these products—the FAC is notably devoid of any claim that JLI *ever* sold Plaintiff a single product or directed anyone else to do so. Instead, Plaintiff alleges that, while he was a minor, unidentified third parties provided him with JUUL products. *Id.* ¶ 63. Plaintiff further concedes that, when he was offered JUUL products by third parties, "the e-cigarette[] w[as] already opened and separated from the packaging." *Id.* ¶ 90. As a result, "*the packaging was never seen by D.P.*," meaning Plaintiff did not read the warning label on JUUL products' packaging, and, of course, would not have seen any other possible alternative statements that he now claims should have been used. *See id.* (emphasis added). Nevertheless, on June 26, 2018, Plaintiff filed a complaint alleging that he had become addicted to nicotine as a result of his misuse of JLI's adult-only nicotine products and sought damages under four product liability causes of action. *See* Dkt. No. 1 ("Complaint"). Following the Court's pre-briefing process—during which Defendant JLI filed a pre-motion letter outlining the pleading deficiencies in the original Complaint, *see* Dkt. No. 25—Plaintiff filed the FAC.

Apart from the removal of Plaintiff's manufacturing defect claim and the insertion of broad, hyperbolic assertions about the nature of JUUL products and JLI's supposed intentions, the FAC offers the same, flawed allegations in support of its causes of action as appeared in the original Complaint. Specifically, the FAC still aims to hold JLI liable for Plaintiff's alleged nicotine addiction through three theories of tort liability:

- *First*, the FAC contends that JLI's products were defectively designed (Claim I), because they achieve their intrinsic purpose—delivering nicotine as an alternative to smoking—and are not unappealing. *See* FAC ¶¶ 72–86.

- *Second*, the FAC alleges that JUUL products contain inadequate warning labels (Claim II), notwithstanding the fact that e-cigarette labels are exclusively governed by the FDA, the labels on the products warn against minors using them and identify their nicotine content, and Plaintiff admits that he would not have seen different or additional warnings had they existed. *See id.* ¶¶ 87–92.

- *Third*, the FAC attempts to hold JLI liable for allegedly negligent design and marketing (Claim III), repackaging his design defect claim as a negligence claim while simultaneously seeking to recover for marketing campaigns that Plaintiff never alleges he saw, much less relied upon. *See id.* ¶¶ 93–98.

Each of the three claims fails as a matter of law and should be dismissed with prejudice.

ARGUMENT

Each of Plaintiff's three claims fails. Moreover, because Plaintiff has already had the opportunity to amend his complaint, this dismissal should be with prejudice. *See*, *e.g.*, *Denny v. Barber*, 576 F.2d 465, 471 (2d Cir. 1978) ("Plaintiff clearly has no right to a second amendment."); *Vaccaro v. Bank of Am., N.A.*, No. 13-cv-2484 (KMK), 2016 WL 4926201, at *9 n.19 (S.D.N.Y. Sept. 15, 2016) (dismissing a complaint with prejudice where court had "already given Plaintiff an opportunity to amend his pleadings").[3]

A. The FAC Fails to State a Claim for Design Defect

To state a claim for design defect under New York law, a plaintiff must plausibly allege that "(1) the product is 'defective' because it is not reasonably safe as marketed; (2) the product was used for a normal purpose; (3) the defect was a substantial factor in causing the plaintiff's injuries; (4) the plaintiff by the exercise of reasonable care would not have both discovered the defect and apprehended its danger; [and] (5) the plaintiff would not have otherwise avoided the injury by the exercise of ordinary care." *Fane v. Zimmer, Inc.*, 927 F.2d 124, 128 (2d Cir. 1991) (internal quotation marks omitted); *see also McCarthy v. Olin Corp.*, 119 F.3d 148, 170 n.25 (2d Cir. 1997). In assessing whether a product was not "reasonably safe," the plaintiff bears the burden of proof to show that "there was a substantial likelihood of harm and *it was feasible to*

[3] Indeed, this Court explained at the parties' October 9, 2018 pre-motion conference that it would permit Plaintiff leave to amend the complaint, but that any successful motion to dismiss filed thereafter likely would result in dismissal with prejudice. Ex. 9, at 2:11–17; 16:7–13 (Oct. 9, 2018 Hearing Tr.).

design the product in a safer manner." *Tompkins v. R.J. Reynolds Tobacco Co.*, 92 F. Supp. 2d 70, 84 (N.D.N.Y. 2000) (emphasis in original) (internal quotation marks omitted); *see also Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013).

The FAC fails to plead the above elements. As addressed below, the FAC asserts that JUUL products are defectively designed primarily because they deliver nicotine, *see* FAC ¶ 83, but delivering nicotine is precisely what JUUL products are supposed to do, *see id.* ¶¶ 63–65, 85; *see also* Dkt. No. 1, ¶¶ 2, 40 (conceding that the JUUL device is designed "for adult smokers" and to "wean addicts off cigarettes").[4] New York law bars design defect claims that, like Plaintiff's, are based on the intrinsic function of the product. Moreover, that a minor unlawfully obtained JUUL products from unscrupulous third parties and thereafter improperly used them does not render these adult-only products "defective." JUUL's products were never designed or intended to be used by minors—they are an alternative for adult smokers—and Plaintiff therefore misused these products. *See* Ex. 8 (noting that the product is "the alternative for adult smokers" and is "**NOT FOR SALE TO MINORS. Keep away from children and pets**." (emphasis in original)). Finally, Plaintiff fails to identify a viable alternative design that would have prevented his claimed addiction and still satisfied adult smokers' desire for the nicotine to which they are addicted. The law does not recognize the FAC's self-contradictory and implausible theory of liability, and this Court should accordingly dismiss Plaintiff's design defect claim.

1. The FAC fails to allege that JUUL products are defective.

a. Nicotine Content

"[A] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer." *Robinson v. Reed–*

[4] "[P]leadings constitute the admissions of a party-opponent and are admissible in the case in which they were originally filed." *U.S. v. McKeon*, 738 F.2d 26, 31 (2d Cir. 1984).

Prentice Div. of Package Mach. Co., 49 N.Y.2d 471, 479 (1980). "This rule, however, is tempered by the realization that some products . . . must by their very nature be dangerous in order to be functional." *Id.* "[M]any products, however well-built or well-designed may cause injury or death. Guns may kill; knives may maim; liquor may cause alcoholism; but the mere fact of injury does not entitle the [person injured] to recover . . . there must be something wrong with the product, and if nothing is wrong there will be no liability." *DeRosa v. Remington Arms Co.,* 509 F. Supp. 762, 769 (E.D.N.Y. 1981) (internal quotation marks omitted). "As a matter of law, a product's defect is related to its condition, *not its intrinsic function*." *Tuosto v. Philip Morris USA, Inc.*, No. 05-cv-9384 (PKL), 2007 WL 2398507, at *12 (S.D.N.Y. Aug. 21, 2007) (emphasis added) (holding that cigarettes are not defective because they are harmful and addictive). Accordingly, "an allegation that [the defendant] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of a design defect." *Simon*, 990 F. Supp. 2d at 405.

The FAC's design defect claim primarily alleges that JUUL products are defective because they deliver an addictive amount of nicotine. *See* FAC ¶ 83; *see also id.* ¶¶ 77, 79 (claiming JUUL products are defective because they contain nicotine and are allegedly "extremely addictive"). However, as noted, this is precisely the sort of broad challenge to a class of products that courts applying New York law have repeatedly rejected as an improper basis for a design defect claim. JLI's products are designed for adult smokers who would like to switch to a nicotine delivery system that satisfies the user's craving for nicotine but does not contain many of the harmful substances commonly found in traditional combustible cigarettes. Dkt. 1, ¶¶ 2, 40 (conceding that JUUL products are "designed for adult smokers" who are addicted to nicotine); 81 Fed. Reg. at 29030 (acknowledgement by the FDA that "switching from combusted cigarettes

to ENDS may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products"). JUUL products do not exist in a vacuum: nicotine has been sold in this country in the form of cigarettes for centuries, and JUUL products are an important alternative to cigarettes. Thus, that JUUL products contain nicotine sufficient to satisfy an adult smoker's desire for nicotine is necessarily an "intrinsic function" of the product. *Cf. Rose v. Brown & Williamson Tobacco Corp.*, 855 N.Y.S.2d 119, 122 (1st Dep't 2008) (finding that a cigarette's utility is not simply "to be lit, burned and inhaled," and that people smoke for the "psychological effect provided by the nicotine").[5]

Further, while Plaintiff would like this Court to make a policy determination regarding the acceptable level of nicotine in ENDS, that is a matter properly left to the FDA and legislative bodies, not the courts. This principle has been repeatedly recognized in the context of cigarettes, the very product that JLI seeks to eliminate. For instance, when confronted with allegations that two cigarette companies "were negligent in designing their product" because "they should have used lower levels of tar and nicotine," the New York Court of Appeals rejected those allegations as an improper basis for a design defect claim. *Adamo v. Brown & Williamson Tobacco Corp.*, 11 N.Y.3d 545, 549 (2008). The court stressed that "[t]o hold . . . that every sale of regular cigarettes exposes the manufacturer to tort liability would amount to a judicial ban on the product. If regular cigarettes are to be banned, that should be done by legislative bodies, not by courts." *Id.* at 551; *see also*, *e.g.*, *Tuosto*, 2007 WL 2398507, at *12 ("allowing the allegation

[5] Such a claim is indistinguishable from a claim that adult beverages like vodka are "defective" because they deliver intoxicating and potentially harmful alcohol to their users, but courts have repeatedly rejected such claims. *See*, *e.g.*, *Cook v. MillerCoors, LLC*, 829 F. Supp. 2d 1208, 1216 (M.D. Fla. 2011) (explaining that alcohol is not "defective," "because the dangers associated with alcohol are well known"); *Greif v. Anheuser-Busch Cos.*, 114 F. Supp. 2d 100, 103 (D. Conn. 2000) (same).

that cigarettes in general are defective to constitute a claim for improper design would contradict congressional policy deeming the sale of cigarettes legal"). This principle—that courts should not substitute their judgment for that of the legislature or regulatory bodies and ban whole classes of products that are already subject to substantial government regulation—is one that has been widely accepted, including outside the context of cigarettes. *See*, *e.g.*, *Clinton v. Brown & Williamson Holdings, Inc.*, 498 F. Supp. 2d 639, 648 (S.D.N.Y. 2007) ("[T]he vast majority of courts have been markedly unreceptive to the call that they displace markets, legislatures, and governmental agencies by decreeing whole categories of products to be outlaws."); *McCarthy v. Sturm, Ruger and Co., Inc.*, 916 F. Supp. 366 (S.D.N.Y. 1996) ("As long as the Legislature permits the manufacture of ammunition, a common law court should not distinguish between different designs and the amount of injury particular bullets cause in judging whether they are defectively designed."). The same logic and deference to legislative bodies on important issues of public policy that guided the courts in those cases counsel in favor of rejecting the Plaintiff's insistence that this Court declare JUUL products defective because they deliver nicotine or could have contained less nicotine.

If the nicotine content of ENDS is to be regulated, the FDA is the agency appointed by Congress to do so. *See* Final Rule, 81 Fed. Reg. at 28976. The FDA can enact nicotine limits on products if it deems it appropriate after weighing the public health policy ramifications of that decision, including the impact on addicted smokers who would be better off switching to ENDS but who may be discouraged from doing so if they do not find ENDS satisfying enough. To date, however, use of ENDS, including JLI's products, remains permissible under federal, state, and local law. This Court should respect the FDA's judgment and not usurp its authority by

impermissibly using a design defect claim to impose sweeping standards on ENDS that may have grave consequences on public health.

Additionally, Plaintiff's claim fails for the independent reason that the addictive nature of nicotine has been well known for many years. A product can only be defective when it is "in a condition not reasonably contemplated by the ultimate consumer." *Robinson*, 49 N.Y.2d at 479; *see also Clinton*, 498 F. Supp. 2d at 648 (recognizing that design defect claims aimed at dangers that are "inherent, open and obvious" must fail). More than thirty years ago, in 1988, the Surgeon General publicly concluded that nicotine is addictive in a report entitled *The Health Consequences of Smoking: Nicotine Addiction*. U.S. Dep't of Health & Human Servs. (1988) ("Surgeon General Report"). As emphasized by the Supreme Court, that report highlighted the existence of "abundant scientific literature demonstrating that '[c]igarettes and other forms of tobacco are addicting'" and "cause[] physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 154 (2000) (quoting Surgeon General Report at 14). In the years since, Congress has issued findings that "[n]icotine is an addictive drug," 21 U.S.C. §387 (2009), and courts have recognized for decades that the addictive nature of nicotine is common knowledge, *see*, *e.g.*, *Small v. Lorillard Tobacco Co., Inc.*, 679 N.Y.S.2d 593, 600 (1st Dep't 1998) (noting on a motion to dismiss that "*[p]laintiffs' claim of ignorance [of nicotine addiction] is implausible* in light of years of pre-1994 press coverage of research on nicotine addiction, as well as the well-known difficulty of quitting smoking" and that "[o]ver the past two decades, the major New York newspapers have published literally hundreds of articles about nicotine addiction and reported numerous public statements by the government and the public health industry to the effect that cigarettes contain a highly addictive drug." (emphasis added)).

Because the risk of nicotine addiction from smoking is common knowledge and Plaintiff could have avoided his alleged addiction through ordinary care, his design defect claim based on the presence of nicotine must fail.

b. pH Levels, Flavors, and Battery Light

The FAC's suggestion that other elements of JUUL products—such as their flavors, their alleged smoothness (*i.e.*, pH level), or the battery indicator light—render the product defective are also not cognizable. *See* FAC ¶¶ 80–82. Plaintiff fails to identify how the FDA-regulated flavors, the amount of "throat hit," or the indicator light are in any way defective. At most, Plaintiff states that JUUL products are satisfying or more enjoyable than combustible cigarettes, but that is not a defect—it is exactly the point of JUUL products for adult smokers. Adults—the *only* intended consumers of JUUL products—enjoy and find utility in flavors when transitioning away from cigarettes, and Plaintiff cannot plausibly allege otherwise. Indeed, Plaintiff does not allege that adult smokers, the intended users of the product, do not enjoy JUUL products.

Absent government regulation, there is no concept under the law that bans flavors for adult products or that requires nicotine products to sting a consumer's throat in an amount that Plaintiff notably fails to quantify. Indeed, alcohol companies have long sold wine coolers, peach schnapps, margaritas, and other tasty beverages; in Plaintiff's unfounded view, each should be deemed "defective" because they facilitate the enjoyable consumption of adult beverages. But that is not the law. *Cf. Cook v. MillerCoors, LLC*, 829 F. Supp. 2d 1208, 1216 (M.D. Fla. 2011) (rejecting plaintiff's attempt to "distinguis[h] Sparks from 'conventional' alcoholic beverages because of the addition of stimulants"). Product defect claims are based on a product's safety, not its desirability. *See*, *e.g.*, *Chavez v. Delta Int'l Machinery Corp.*, 13 N.Y.S.3d 482, 484 (2d Dep't 2015) (noting that the definition of a design defect under New York law is linked to

inherent risk). The law does not require that JLI make its products taste bad and kick like a mule such that no consumer would ever want to use them, but that is precisely what Plaintiff's defective theory seeks to impose.

In any event, the FDA has the power to impose product standard regulations regarding flavors or features that could affect "throat hit," but it has not. To the contrary, the FDA has expressly stated that flavored ENDS products "may be important to adult smokers seeking to transition away from cigarettes," and it has indicated an intent to regulate channels through which flavored products may be sold. Ex. 6, at 5. Indeed, the FDA issued an advanced notice of proposed rulemaking on March 21, 2018 to examine "how certain flavors may help adult cigarette smokers reduce cigarette use and switch to potentially less harmful products," balanced against potential usage by minors. 83 Fed. Reg. 12294. This is a policy issue for the FDA to regulate after hearing from all interested stakeholders and balancing competing public health concerns; it is not, as Plaintiff suggests, for the Court to adjudicate under the guise of a strict liability product defect claim under state law. This is especially true given that any "product standards" enacted by the FDA preempt state law, 21 U.S.C. § 387p(a)(2)(A), and that the FDA is currently examining how best to regulate ENDS flavors.

In any event, the FAC does not allege that Plaintiff was led to use JUUL products due to their pH level, flavors, or lights, or that he did not know full well that JLI's products were addictive. Instead, Plaintiff alleges that he used the product because of peer pressure. *See id.* ¶ 63. Accordingly, those alleged "defects," which are actually nothing of the sort, cannot form the basis of a design defect claim. *See Simon*, 990 F. Supp. 2d at 403 (alleged design defect must be a "substantial factor in causing plaintiff's injury").

2. The FAC fails to allege a feasible alternative design.

The FAC also fails to plead a viable alternative design. "A plaintiff is required to prove the existence of a feasible alternative design which would have prevented the accident." *Am. Guarantee & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09-cv-8357 (BSJ) (HBP), 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010). For tobacco products, plaintiffs must demonstrate that the proposed alternative would still give the same amount of pleasure to the user. *See Adamo*, 11 N.Y.3d at 550.

None of the suggestions proffered in the FAC for possible changes to the JUUL device or JUULpods amount to a feasible alternative design. The FAC first posits that JLI could have potentially designed an e-cigarette that "contain[ed] far less nicotine" or whose nicotine content was "less likely to addict its users." FAC ¶ 79. According to Plaintiff's own admissions, however, JUUL products are designed "for adult smokers" and to "wean addicts off cigarettes." *See* Dkt. No. 1, ¶¶ 2, 40. In other words, the purpose of JUUL products is not nicotine *reduction*, but rather nicotine *satisfaction* through a method that does not involve the combustion of toxicants. Indeed, the packaging on JUULpods stated at the time that Plaintiff acquired JUUL products that those products contained nicotine "approximately equivalent to about 1 pack of cigarettes." Ex. 8. Plaintiff's proposed alternative design effectively asks JLI to eliminate JUUL products' inherent function of delivering nicotine to satisfy an existing addicted smoker's desire for nicotine, which is not a legitimate "alternative design." *See Clinton*, 498 F. Supp. 2d at 648 (noting that "reduced carcinogen" and "non-addictive" cigarette designs "are plainly not feasible alternative designs in any meaningful sense," but are instead an attempt to impose a "virtual ban on cigarettes"). As the Court of Appeals stressed in *Adamo v. Brown & Williamson Tobacco Corp.*, "satisfying the consumer is the only function [of a cigarette]," and a proposed alternative is not feasible if it cannot give the same amount of "pleasure to a smoker." 11 N.Y.3d at 550–

51. The same logic applies here: because Plaintiff has not alleged a feasible alternative, the claim must fail. *See*, *e.g.*, *Fabiano v. Philip Morris Inc.*, 909 N.Y.S.2d 314, 319–20 (N.Y. Sup. Ct. 2010) (noting that *Adamo* "established a risk-satisfaction analysis" for cigarettes, and that plaintiffs cannot offer as a proposed alternative a product that is "devoid of all of [the] major properties" of cigarettes).

While the FAC also suggests that JLI could have designed a product that had pH levels high enough to irritate consumers' throats, or that lacked flavors, or that did not have a battery indicator that lights up, FAC ¶¶ 80–82, Plaintiff does not plausibly allege that users would find JLI products as satisfying with those changes, *see Fabiano*, 909 N.Y.S.2d at 319–20. There is no duty under the law to mimic all of the unenjoyable attributes of cigarettes, which would likely *discourage* adults from switching away from those deadly products. Further, there is nothing in the FAC to suggest that these changes would have "prevented the accident" (*i.e.*, Plaintiff's alleged addiction). *See Am. Guarantee & Liab. Ins. Co.*, 2010 WL 5480775, at *3. Because the FAC ties Plaintiff's use of JUUL products to peer pressure and not to the products' pH levels, flavors, or lights, he has not adequately alleged causation.

3. The FAC concedes that D.P. did not use JUUL products in their intended manner.

Finally, by pleading that Plaintiff's alleged injury occurred when, as a 15-year-old, he improperly used a product designed for adults and explicitly labeled that it should not be sold to or used by minors, the FAC further dooms its design defect claim. Under New York law, "a defectively designed product is one that is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its *intended use*." *Hartnett v. Chanel, Inc.*, 948 N.Y.S.2d 282, 285 (1st Dep't 2012) (emphasis added) (internal quotation marks omitted). Plaintiffs cannot recover for design defect claims when they used the relevant product in an

unintended manner. *See*, *e.g.*, *Amatulli v. Delhi Constr. Corp.*, 77 N.Y.2d 525, 532–33 (1991) (no liability for manufacturer of above-ground pool after plaintiff was injured after installing it as a below-ground pool); *Bombara v. Rogers Bros. Corp.*, 734 N.Y.S.2d 617 (2d Dep't 2001) (no liability where individual was injured riding on the rear of an open trailer designed to transport construction equipment); *Landrine v. Mego Corp.*, 464 N.Y.S.2d 516, 518 (1st Dep't 1983) ("Digestion of a balloon is not an intended use, and to the extent it is a foreseeable one, it is a misuse of the product for which the guardian of children must be wary.").

Plaintiff's claimed injuries stem from his *misuse* of JUUL products, which forecloses his ability to recover for an alleged design defect. As Plaintiff has alleged, JUUL products are designed "for adult smokers" and to "wean addicts off cigarettes." *See* Dkt. No. 1, ¶¶ 2, 40. Indeed, at all relevant times, the packaging for JUULpods warned that they were "the alternative for adult smokers," "**NOT FOR SALE TO MINORS. Keep away from children and pets**[,]" and that "1 JUULpod contains – 0.7mL with 5% nicotine by weight //approximately equivalent to about 1 pack of cigarettes." Ex. 8 (emphasis in original). Yet Plaintiff was neither an adult nor a smoker when he used the product. *See* FAC ¶¶ 60, 64. Further, as a minor in New York State, Plaintiff was not of legal age to use JUUL products or any other tobacco product. *See* N.Y. Pub. Health § 1399-cc(2) (prohibiting the sale of e-cigarettes to individuals under 18 years of age). A minor cannot misuse an otherwise legal adult-only product and then hold the manufacturer liable for such misuse under the guise of product liability; for instance, a minor's illegal consumption of beer or vodka does not suddenly render those products defective. *See*, *e.g.*, *Patterson v. Rohm Gesellschaft,* 608 F. Supp. 1206, 1213 (N.D. Tex. 1985) (stressing that "tort law is premised upon fairness, making individuals responsible for their own acts," and that the "ability of a [product] manufacturer to spread the loss is not a sufficient basis" for requiring

the "subsidiz[ation]" of the "the actions of those who use" the manufacturer's products "wrongfully"). Moreover, Plaintiff concedes that he had previously tried cigarettes, FAC ¶ 64, does not allege that he did not know that JUUL products contain nicotine or was unaware that nicotine is addictive, and does not claim that he believed it was appropriate for him to use JLI's adult-only nicotine products. That the FAC's design defect claim is premised on such misuse of JUUL products renders that claim fatally deficient.

B. The FAC Fails to State a Claim for Failure to Warn

The FAC's second claim for relief—failure to warn—alleges that JUUL products were "not labeled with an adequate warning." FAC ¶ 88. This claim is foreclosed as a matter of law because it is preempted by applicable FDA regulations. The claim is also defective because (1) the FAC does not plausibly allege proximate causation because Plaintiff concedes that he would not have seen any additional or alternative warnings on the packaging, and (2) JLI did not have a duty to warn about the obvious and well-known risks of becoming addicted to nicotine, which, in any event, Plaintiff does not allege he did not know about. *See Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 84 (S.D.N.Y. 2001) ("A failure to warn claimant must show (1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm.").

1. The failure to warn claim is preempted by federal law.

The FDA has promulgated regulations regarding ENDS that expressly preempt the FAC's failure to warn claim. Federal preemption of state law "may be either express or implied," and "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983) (internal quotation marks omitted). Under express preemption, "Congress explicitly may define the extent to which its enactments pre-empt state law." *Schneidewind v.*

ANR Pipeline Co., 485 U.S. 293, 299 (1988). "[W]hen Congress has made its intent known through explicit statutory language, the courts' task is an easy one." *English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990) (internal citation omitted).

The Family Smoking Prevention and Tobacco Control Act ("TCA") (21 U.S.C. §§ 387–387u) provides the FDA with the authority to regulate the manufacture, labeling, marketing, and distribution of tobacco products to protect public health. 21 U.S.C. § 387, *et seq*. Under the FDA's May 10, 2016 Final Rule, the agency deemed e-cigarettes "tobacco products," bringing them under the TCA's mandate and FDA oversight. 81 Fed. Reg. at 28976. Accordingly, the TCA's express preemption provision—which states that "no State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to tobacco product . . . labeling"—applies to ENDS. *See* 21 U.S.C. § 387p(a)(2)(A); *see also id.* § 321(k) (defining "label" as "a display of written, printed, or graphic matter upon the immediate container of any article"). This definition applies not just to the exterior labeling on ENDS packaging, but *also to the device itself* because it governs all "written, printed, or graphic matter . . . *upon any article* or any of its containers or wrappers." 21 U.S.C. § 321(m) (emphasis added). Put simply, the TCA and the Final Rule provide the FDA with exclusive authority over labeling for ENDS, and the FDA has exercised that authority, *see* 81 Fed. Reg. at 28988 (21 C.F.R. § 1143.3) (setting forth requirements for warning labels on ENDS).

The FAC's failure to warn claim is expressly preempted by this statutory and regulatory framework. As Judge William H. Orrick emphasized when confronted with a similar claim in *Colgate v. JUUL Labs, Inc.*, 345 F. Supp. 3d 1178 (N.D. Cal. 2018),

> [t]he FDA has unambiguously put forth the required language and placement of the nicotine warning label, down to the font and placement of the label.

> Considering the statutory and regulatory scheme in its entirety, I find that the FDA, through its authority under the TCA has prescribed the precise language and placement of warning labels on covered tobacco products such as ENDS under 21 C.F.R. §§ 1143.3(a)(1)(2). . . . [U]nder the TCA's preemption provision, states and political subdivisions of states may not enact labeling requirements or warnings contrary or in addition to those prescribed under 21 C.F.R. §§ 1143.3(a)(1)(2).

Id. at 1188; *see also In re Fontem*, No. 15-cv-01026, 2016 WL 6520142, at *3 (C.D. Cal. Nov. 1, 2016) (finding that "the preemption analysis is straightforward: the FDA, under the authority it possesses under the [TCA], has promulgated a labeling requirement that applies to e-cigarettes," which means that "state labeling requirements that apply to e-cigarettes that are 'different from, or in addition to' the FDA's requirement are preempted" (quoting 21 U.S.C. § 387p(a)(2)(A))). Additionally, this preemption language precludes claims based on labeling whether before or after the August 8, 2016 date of the FDA's final order. *See In re Fontem*, 2016 WL 6520142, at *8; *Colgate*, 345 F. Supp. 3d at 1189. Based on this analysis, the *Colgate* and *In re Fontem* courts dismissed with prejudice claims based on allegedly deficient warning labels . *See id.*; *In re Fontem*, 2016 WL 6520142, at *6. This Court should do the same.

2. The FAC fails to plead causation.

In addition to being preempted, the failure to warn claim also fails because the FAC affirmatively concedes that an additional or alternate warning label would have had no effect on the Plaintiff. "A plaintiff proceeding under a failure-to-warn theory in New York must demonstrate that the failure to warn adequately of the dangers of a product was a proximate cause of his or her injuries." *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993). It is thus the plaintiff's burden to allege "that if adequate warnings had been provided, the product would not have been misused." *Banks v. Makita, U.S.A., Inc.*, 641 N.Y.S.2d 875, 877 (2d Dep't 1996). "Absent proof of causation," it is "proper[]" for courts to dismiss failure to warn claims. *Id.*

The FAC does not and cannot allege that a different warning label would have prevented Plaintiff's misuse of JUUL products because the FAC concedes that "the packaging [of JUUL e-cigarettes] was never seen by D.P." FAC ¶ 90. Thus, no alternative warning label—however explicit—would have prevented Plaintiff's alleged injury. *Cf. Repka v. Arctic Cat, Inc.*, No. 19971117, 2004 WL 750699, at *7 (N.Y. Sup. Ct. Feb. 27, 2004) (finding that "[p]laintiff's failure to heed the warnings that were given"—and not the alleged "inadequacy" of those unconsulted warnings—"were causative of [his] accident"). Further, Plaintiff does not allege that he did not know that JUUL products contain nicotine, or that he would not have used them had he known that. This failure to plead proximate causation provides independent grounds for dismissal. *See*, *e.g.*, *Jackson v. General Motors Corp.*, 770 F. Supp. 2d 570, 578–79 (S.D.N.Y. 2011) ("Plaintiff's failure to warn claims must also be dismissed because the claims are preempted and, in any event, Plaintiffs failed to adequately plead proximate causation.").

The FAC's failure to warn claim is likewise foreclosed by the fact that the packaging for JUULpods explicitly stated that the product was "for adult smokers" and should not be sold to or used by minors: "**NOT FOR SALE TO MINORS. Keep away from children and pets**." *See* Ex. 8 (emphasis in original).[6] If Plaintiff had heeded this warning, he would not have used JUUL products. Further, the packaging on JUUL products plainly disclosed, at all relevant times, that "1 JUULpod contains – 0.7mL with *5% nicotine* by weight//*approximately equivalent to about 1 pack of cigarettes*." *Id.* (emphasis added). Thus, in order to conclude that the FAC plausibly alleges that inadequate warnings were the proximate cause of Plaintiff's alleged nicotine addiction, one would need to believe that Plaintiff did not know that nicotine is addictive. Not

[6] The FAC's deletion of the original Complaint's references to warnings on JUUL's products, *see*, *e.g.*, Dkt. No. 1 ¶¶ 75, 76, does not prevent the Court from reviewing them: those warnings are integral to the FAC and subject to judicial notice. *See supra* n.2.

only does Plaintiff fail to allege as much, but such an allegation—even if made—would not be reasonable or plausible in light of the long, well-known history that nicotine is addictive. *See* Section A.1.a.; *see also Brown & Williamson*, 529 U.S. at 154 (noting the 1988 Surgeon General Report that nicotine in cigarettes is addictive); *Small*, 679 N.Y.S.2d at 600 (finding on a motion to dismiss that "*[p]laintiffs' claim of ignorance is implausible* in light of years of pre-1994 press coverage of research on nicotine addiction, as well as the well-known difficulty of quitting smoking" (emphasis added)). This Court should therefore dismiss the failure to warn claim.

3. JLI did not have a duty to warn of an obvious risk.

Finally, JLI did not have a duty to warn Plaintiff about the risks of nicotine because those risks are obvious. "New York recognizes two exceptions to a failure to warn claim: (1) where the injured party was fully aware of the hazard through general knowledge, observation or common sense, *i.e.*, []he was a knowledgeable user, and (2) where the risks are open and obvious." *Frazer v. ITW Food Equip. Grp. LLC,* No. 11-cv-9699 (CS), 2013 WL 6164486, at *5 (S.D.N.Y. Nov. 22, 2013) (internal quotation marks omitted); *see also*, *e.g.*, *Kerr v. Koemm*, 557 F. Supp. 283, 287 (S.D.N.Y. 1983) ("The rule that a manufacturer has no duty to warn of an obvious danger is well established."); *DePasquale v. Morbark Indus., Inc.*, 633 N.Y.S.2d 543, 544 (2d Dep't 1995). Both exceptions apply here. *First*, as emphasized above, Plaintiff does not allege that he did not know or that he lacked the common sense to know that nicotine is addictive. *Cf.* FAC ¶ 64 (acknowledging that Plaintiff had previously tried cigarettes). *Second*, numerous courts and legislative bodies have recognized that the addictive properties of nicotine and dangers of cigarette smoking have long been known to the community. *See supra* A.1.a. Indeed, the FDA recently stressed that "[t]he Surgeon General has *long recognized* that the addictive nature of tobacco products is due to the presence of . . . nicotine," citing to the Surgeon

General Report from *30 years ago*. *See* 81 Fed. Reg. at 28981 (emphasis added). JLI's multiple, clear statements regarding the nicotine content of its products were sufficient.

C. The FAC Fails to State a Claim for Negligence

The FAC's third and final claim asserts that JLI negligently designed and marketed its products, recycling the earlier design defect claim and adding in allegations regarding marketing that Plaintiff never even alleges he saw, much less relied upon. However, repackaging the design defect claim does not cure it of its underlying deficiencies, nor can JLI be held liable under a negligent marketing theory for alleged damages that were clearly not caused by any marketing campaign. "To state a cause of action for negligence, the plaintiff[] must show: (1) that [the defendant] owed [him] a duty, or obligation, recognized by law, (2) a breach of the duty, (3) a reasonably close causal connection between [defendant's] conduct and the resulting injury[,] and (4) loss or damage resulting from the breach." *McCarthy*, 119 F.3d at 156 (internal quotation marks omitted). Because Plaintiff has failed to plausibly allege duty, breach, or causation, this claim fails.

1. The FAC fails to plead negligent design.

Plaintiff's negligent design claim fails for the same reasons that his design defect claim fails. "New York courts generally consider strict products liability and negligence claims to be functionally synonymous." *S.F. v. Archer Daniels Midland Co.*, 594 F. App'x 11, 12 (2d Cir. 2014); *see also*, *e.g.*, *Denny v. Ford Motor Company*, 87 N.Y.2d 248, 257–58 (1995). To the extent the two analyses differ, the showing required to state a claim for negligent design is *higher* than that required for design defect because it requires a breach of a reasonable standard of care. *See Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 107 (1983).

Given this parallel, the pleading deficiencies identified above in Section A—in particular the FAC's improper insistence on banning a whole category of product and failure to plead a

feasible alternative design—are fatal to its negligence claim. *See Archer Daniels Midland*, 594 F. App'x at 12–13 (rejecting both strict liability and negligence design defect claims due to the complaint's pursuit of an "outright ban" at the expense of pleading an alternative design). JUUL products do not violate the law, and numerous courts have held that combustible cigarettes—which Plaintiff does not dispute are more dangerous than ENDS—are not defective simply because they are addictive and can be harmful. *See supra* A.1.a. JLI therefore has no duty to design an e-cigarette without addictive levels of nicotine. *Contra* FAC ¶ 94.

Moreover, the FAC's negligence claim also fails because Plaintiff obtained JUUL products not through JLI, but through the illegal actions of third parties. Selling tobacco products to minors is illegal under New York law, *see* N.Y. Pub. Health § 1399-cc(2), and manufacturers generally "are under no duty to anticipate and prevent criminal conduct by others." *Elsroth v. Johnson & Johnson*, 700 F. Supp. 151, 163 (S.D.N.Y. 1988); *cf. Bertovich v. Advanced Brands & Imp., Co.*, No. 05-cv-74 (IMK), 2006 WL 2382273, at *7–13 (N.D. W. Va. Aug. 17, 2006) (compiling cases dismissing claims against alcohol manufacturers for allegedly enticing minors to use alcohol where those minors had obtained alcohol illegally from third parties).

Finally, because the FAC does not allege that the "reduced . . . 'throat hit'" or flavors led to Plaintiff's use of JUUL products—which it instead attributes to peer pressure—it likewise cannot establish causation for purposes of its negligent design claim. *See* FAC ¶¶ 63, 71. That claim should therefore be dismissed in its entirety.

2. The FAC fails to plead negligent marketing.

Negligent marketing claims raised under New York law have historically triggered skepticism from the courts. *See*, *e.g.*, *Hamilton v. Beretta U.S.A. Corp.*, 96 N.Y.2d 222, 239 (2001) (describing a negligent manufacturing claim as one that sought to "impos[e] [a] novel

theor[y] of tort liability"). The claim here fares no better. While the FAC seeks to base its cause of action on allegations that JLI "market[ed] the product as a cool, hip, stylish accessory" and used purportedly "youth-centric media such as Twitter and Instagram," FAC ¶ 71, this is simply not a grounds for imposing liability. *See, e.g.*, *Hakki v. Zima Co.*, No. 03-9183, 2006 WL 852126, at *3 (D.C. Super. Ct. Mar. 28, 2006) (holding advertisements "employ[ing] attractive models" or "social situations with which minors might identify" are not actionable). Additionally, there is no "reasonably close causal connection" between JLI's marketing campaigns and Plaintiff's supposed injury, *McCarthy*, 119 F.3d at 156—the allegations have nothing to do with his alleged injury. In fact, the FAC is devoid of *any* allegation that Plaintiff *ever* saw a JUUL advertising campaign or JUUL-related social media post, much less that either caused him to use JUUL products. As a result, the negligent marketing claim must also fail.

CONCLUSION

For all of the foregoing reasons, JUUL Labs, Inc. respectfully requests that the Court grant this motion to dismiss with prejudice.

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